IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYOWA HAKKA BIO, CO., LTD, BIOKYOWA, INC., KYOWA HAKKA BIO U.S. HOLDINGS, INC., and KYOWA HAKKA U.S.A., INC.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	**NO. 17-313**
AJINOMOTO CO., INC., AJINOMOTO ANIMAL NUTRITION GROUP, INC., AJINOMOTO NORTH AMERICA, INC. AJINOMOTO HEARTLAND, INC. and AJINOMOTO WINDSOR, INC.,	:	
Defendants.	:	

Goldberg, J. **June 19, 2020**

MEMORANDUM OPINION

Plaintiffs Kyowa Hakko Bio, Co., Ltd, BioKyowa, Inc., Kyowa Hakko Bio U.S. Holdings, Inc., and Kyowa Hakka U.S.A., Inc. (collectively, "Plaintiff") allege infringement of U.S. Patent No. RE 45,723, entitled "Process for Producing Amino Acids" by Defendants Ajinomoto Co., Inc., Ajinomoto Animal Nutrition Group, Inc., Ajinomoto North America, Inc., Ajinomoto Heartland, Inc., and Ajinomoto Windsor, Inc. (collectively, "Defendant").

Following a claim construction hearing, pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), United States Magistrate Judge Richard A. Lloret issued a Report and Recommendation on three disputed claim terms: (1) "average particle size"; (2) "adding crystals of the amino acid . . . to the medium"; and (3) "before crystals of the amino acid deposit in the medium." Both parties have filed objections to Judge Lloret's rulings on the first two terms. I

have reviewed those objections and Judge Lloret's Report. For the following reasons, I will overrule all objections and adopt Judge Lloret's Report and Recommendation in its entirety.

I. FACTUAL AND PROCEDURAL BACKGROUND

Judge Lloret's October 9, 2019 Report and Recommendation sets forth a detailed summary of the invention at issue and the dispute between the parties. Rather than repeating the background of this case, I will recap the facts relevant to consideration of the parties' objections.

The patent-in-suit, U.S. Patent No. RE 45,723 (the "'723 patent"), was issued by the United States Patent and Trademark Office on October 6, 2015. Claim one of the '723 patent (as amended during reissue proceedings) sets forth a process for making amino acids, as follows:

> 1. A process for producing an amino acid, which comprises:
> culturing a microorganism having an ability to produce the amino acid in a medium,
> adding crystals of the amino acid having an average particle size of 7 to 50 μm to the medium at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium so that the concentration of the crystals of the amino acid becomes 0.5 g/l or more,
> culturing the microorganism having the ability to produce the amino acid in the medium,
> allowing the crystals of the amino acid to grow to crystals of the amino acid having an average particle size of 30 μm or more and accumulate in the medium, and
> recovering the crystals of the amino acid from the culture by separating the microorganism producing the amino acid and the accumulated crystals of the amino acid based on the difference in particle size or specific gravity between them.

(Id. ¶ 48.)

Claim 2 is the same as claim 1 except that, in claim 1, the "adding crystals" step concludes: "so that the concentration of the crystals of the amino acid becomes 0.5 g/l or more," while, in claim 2, the "adding crystals" step concludes: "so that the total surface area of the crystals of the amino acid in the medium becomes 0.02 m2/1 or more." (Id. ¶ 49.) The second through fourth

steps of Claims 1 and 2 define a particular type of Direct Crystal Precipitation ("DCP") process. (Id. ¶ 50.)

Following claim construction briefing and a Markman hearing, Judge Lloret issued a Report and Recommendation finding that:

- The term "average particle size" is indefinite, thus rendering claims 1 and 2 of the '723 patent invalid.
- The term "adding crystals of the amino acid . . . to the medium" means "[i]ntroducing crystals to the medium that were not there before, which are the same crystals that the claim later requires 'grow . . . and accumulate in the medium.'"
- The term "before crystals of the amino acid deposit in the medium" mean "before the point in time when more than a slight amount of microcrystals would begin depositing in the medium, unaided by the addition of seed crystals."

The parties each filed objections. Plaintiff challenges the finding that "average particle size" is indefinite, while Defendant challenges the construction of the term "adding crystals of the amino acid . . . to the medium."

II. STANDARD OF REVIEW

A. Standard of Review of a Magistrate Judge's Report and Recommendation

Review of a report and recommendation is governed by 28 U.S.C. § 636(b)(1)(C) and Federal Rule of Civil Procedure 72(b). The district court "shall make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made" and "may also receive further evidence or recommit the matter to the magistrate judge with instructions." 28 U.S.C. § 636(b)(1)(C). Similarly, Rule 72(b)(3) requires *de novo* review of any recommendation that is dispositive of a claim or defense of a party.

Claim construction determinations in an R&R are reviewed *de novo*. See St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., 691 F. Supp. 2d 538, 542 (D. Del. 2010). Claim construction falls "exclusively within the province of the court," not that of the

jury. Teva Pharm. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 325 (2015) (quoting Markman, 517 U.S. at 372). It is proper for courts to "treat the ultimate question of the proper construction of the patent as a question of law in the way that [courts] treat document construction as a question of law." Id. at 325 (noting that when the court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law, however, underlying factual determinations are reviewed for clear error).

B. Standards for Claim Construction

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. Markman, 52 F.3d at 976. Claim construction, which serves this purpose, is a matter of law exclusively for the court. Id. at 979. "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" SoftView LLC v. Apple Inc., No. 10-389, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed. Cir. 2005)).

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips, 415 F.3d at 1312 (internal quotation marks omitted). The focus of a court's analysis must therefore begin and remain on the language of the claims, "for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'" Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2). The terms used in the claims bear a "heavy presumption" that they mean what they say and have their ordinary and customary meaning. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). That ordinary meaning "is the meaning that the term would have to

a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313.

Generally, a person of ordinary skill in the art would not understand the ordinary and customary meaning of a claim term in isolation. As such, the ordinary meaning may be derived from a variety of sources including intrinsic evidence, such as the claim language, the written description, drawings, and the prosecution history, as well as extrinsic evidence, such as dictionaries, treatises, or expert testimony. Dow Chem. Co. v. Sumitomo Chem. Co., Ltd., 257 F.3d 1364, 1373 (Fed. Cir. 2001).

The "most significant source" of authority is "the intrinsic evidence of record, i.e., the patent itself, including the claims, the patent specification[1] and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see also Phillips, 415 F.3d at 1313 (holding that a person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the specification). The specification "is the single best guide to the meaning of a disputed term" and is usually dispositive as to the meaning of words. Vitronics, 90 F.3d at 1582. Although it is improper to import limitations from the specification into the claims, "one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). On occasion, "the specification may reveal a special definition given to a claim term . . . that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."

[1] The specification is "that part of a patent application which precedes the claim and in which the inventor specifies, describes, and discloses the invention in detail." McCarthy's Desk Encyclopedia of Intellectual Property 408 (2d ed. 1995).

Phillips, 415 F.3d at 1316. The specification may also "reveal an intentional disclaimer, or disavowal, of claim scope by the inventor . . . [, which] is regarded as dispositive." Id. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Renishaw, 158 F.3d at 1250.

If ambiguity still exists after considering all the intrinsic evidence, the court may rely on extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980. "[D]ictionaries, and especially technical dictionaries, . . . have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology." Phillips, 415 F.3d at 1318. Additionally, expert testimony can provide background on the technology at issue, explain how it works, speak to what a person of ordinary skill in the art would understand, and establish that a particular term has a particular meaning in the pertinent field. Id. Notably, however, extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

Ultimately, during claim construction, "[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." Phillips, 415 F.3d at 303.

III. DISCUSSION

A. Whether Judge Lloret Erred in Finding the Term "Average Particle Size" to be Indefinite

Plaintiff's sole objection focuses on Judge Lloret's finding that the term "average particle size" is ambiguous, which, if accepted would render claims 1 and 2 of the patent invalid. Judge Lloret concluded that this term was indefinite because persons of ordinary skill in the art would have significant doubt about whether to interpret the phrase to call for application of an arithmetic mean, volume weighted averaging, or some other form of measurement. He noted that the "ordinary English meaning" of the phrase is the arithmetic mean—*i.e.*, the size of each of the particles in a given set, added together, and divided by the number of particles. However, Judge Lloret also concluded that, in the context of the patent-in-suit, it was unclear whether a person of ordinary skill in the art would construe "average particle size" to also mean a volume weighted average diameter. Reviewing the intrinsic and extrinsic evidence, Judge Lloret remarked that, on one hand, the patent did not mention "volume weighted average" or any other weighted or volume-based averaging technique and, thus, the use of an arithmetic mean made sense in the context of the patent. On the other hand, he noted that Figure 1 of the patent appeared to disclose the use of a different technique, other than an arithmetic mean, to calculate "average particle size." Turning to the extrinsic evidence, Judge Lloret observed that statements made by Plaintiff in European patent proceedings suggested that "average particle size" meant volume weighted average particle size. Concluding that the meaning of the term was ambiguous to a person of ordinary skill in the art, Judge Lloret held that the phrase "average particle size," as used in the '723 patent, is indefinite.

Plaintiff offers several challenges to Judge Lloret's finding of indefiniteness. First, it contends that the R&R erroneously failed to consider and apply the correct legal standards for

patent invalidity. Second, Plaintiff urges that Judge Lloret's finding that a skilled artisan would understand average particle size based on a plain reading of the patent should have ended the analysis. Third, Plaintiff asserts that Judge Lloret ignored significant facts regarding Figure 1 of the patent. And finally, Plaintiff claims that Judge Lloret erred by relying on communications with the European patent office.

1. Whether the R&R Failed to Consider the Legal Standards for Patent Invalidity

Plaintiff first contends that the R&R failed to consider the legal standards and burdens for invalidating a patent. According to Plaintiff, because patents enjoy a presumption of validity, a declaration of invalidity, including by reason of indefiniteness, must be proven by clear and convincing evidence. (Pl.'s Objs. 11.) Citing to Justice Breyer's concurrence in the 2011 Supreme Court case of Microsoft Corp. v. I41 Ltd. Partnership, 564 U.S. 91, 114 (2001), Plaintiff argues that Judge Lloret merely found a dispute of fact as to the meaning of the term "average particle" size—not clear and convincing evidence of indefiniteness—and thus improperly invalidated claims 1 and 2 of the patent-in-suit.

Plaintiff, however, only discusses the general burden of proof for invalidity defenses without concurrently addressing the well-defined standards for legally invalidating a patent's claim for indefiniteness during claim construction. The indefiniteness legal standard was recently revamped by the United States Supreme Court in Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898 (2014). Prior to Nautilis, a claim could only be held indefinite if it was "insolubly ambiguous, and no narrowing construction [could] properly be adopted." Dow Chem. Co. v. Nova Chems. Corp., 803 F.3d 620, 630 (Fed. Cir. 2015) (quoting Exxon Research & Eng'g Co. v. U.S., 265 F.3d 1371, 1375 (Fed. Cir. 2001)). Rejecting that "insolubly ambiguous" standard and recognizing the importance of a public-notice function of definiteness, the Supreme Court

loosened the indefiniteness standards and held that a patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." Nautilus, 572 U.S. at 910. "It cannot be sufficient that a court can ascribe *some* meaning to a patent's claims." Id. at 911. Rather, under Nautilis, there is an indefiniteness problem if the claim language "might mean several different things and 'no informed and confident choice is available among the contending definitions.'" Id. at 911 n.8 (quoting Every Penny Counts, Inc. v. Wells Fargo Bank, N.A., 4 F. Supp. 3d 1286, 1291 (M.D. Fla. 2014)). Ultimately, "[t]he claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1371 (Fed. Cir. 2014).

The Federal Circuit has noted that the Nautilis standard is particularly important where, as in the case before me, different approaches to measurement are involved. Dow Chem., 803 F.3d at 630. Thus, in order to overcome an indefiniteness challenge, "the patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select." Id. (citation omitted) (finding the claim term including the phrase "slope of strain" indefinite where the patent did not teach where and how the "slope of strain hardening" should be measured and there were multiple methods available); see also Teva Pharms. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1341 (Fed. Cir. 2015) (holding claim indefinite where molecular weight could be measured three different ways and would yield different results, and that the patent and prosecution history did not provide guidance as to which measure to use).

As noted above, Judge Lloret recommended, in the context of a claim construction, that the phrase "average particle size" was indefinite. "Indefiniteness is a matter of claim construction,

and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction." Cephalon, Inc. v. Slayback Pharma Ltd. Liabl Co., No. 17–11542020 WL 1983730, at *19 (D. Del. Apr. 27, 2020) (citing Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008), abrogated on other grounds by Nautilus, 572 U.S. at 901). "The internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law." Teva Pharm. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1342 (Fed. Cir. 2015). However, as in claim construction, in making an indefiniteness determination, the district court may make "factual findings about extrinsic evidence relevant to the question, such as evidence about knowledge of those skilled in the art." BASF Corp. v. Johnson Matthey Inc., 875 F.3d 1360, 1365 (Fed. Cir. 2017). "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." Cox Commc'ns, Inc. v. Sprint Commc'n Co. LP, 838 F.3d 1224, 1228 (Fed. Cir. 2016) (alteration in original)). Not every determination of indefiniteness contains genuine disputes over the underlying facts material to the inquiry. Berkheimer v. HP, Inc., 881 F.3d 1360, 1368 (Fed. Cir. 2018).

Consistent with these principles, Judge Lloret applied the correct standards. At the outset of the R&R, he remarked that there are various ways to measure particles, including by arithmetic means, by volume-weighted averaging, and by surface-weighted averaging. (R&R 6–9.) He further noted that "[t]he heart of the invention focuses on adding a specific size and quantity of crystals at a specific time in the fermentation process to produce the desired effect" and thus "[m]easurement of the average size of the seed crystals is not a peripheral issue." (R&R 20.) Thereafter, reviewing the specification and the prosecution history, he found, as a matter of law, that the patent specification offered conflicting guidance as to the proper measurement technique

in order to determine "average particle size." He further remarked that the extrinsic evidence, in the form of Plaintiff's statements in a European patent proceeding, clearly and convincingly suggested that the measurement could refer to a volume weighted diameter mean. Citing the Federal Circuit decision in Dow Chemical, *supra*, Judge Lloret concluded that because the patent did not disclose a single known measurement approach such that a person of ordinary skill in the art would understand which approach to select in the context of the patent, the claim term was indefinite, thus rendering its associated claims invalid.

Ultimately, there were no genuine issues of material fact that required resolution by a factfinder or otherwise foreclosed the legal conclusion of indefiniteness.[2] As such, I find that Judge Lloret applied the appropriate standards in reaching his recommendation.

2. Whether the Plain Reading of the Patent Should Have Ended the Claim Construction

Plaintiff next asserts that Judge Lloret erred by extending his analysis past a plain reading of the patent. Plaintiff points out that the R&R states that "[u]sing an arithmetic mean as an averaging technique makes sense in the context of the process claimed by the patent" and that Defendant's contrary proposed construction was not supported by the specification. According to Plaintiff, these conclusions, standing alone, should have ended the claim construction and resulted in a finding that Plaintiff's construction was correct. (Pl.'s Objs. 5 (citing Thorner v. Sony Computer Entm't Am., LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012).)

[2] Judge Lloret commented that the parties' "highly qualified and credible experts" were at odds about what the phrase means. He stated, however, that their disagreement did not create a factual dispute that stymied claim construction because interpretation of a patent's language is a legal issue, not a factual issue. Nevertheless, he noted that their disagreement reinforced his conclusion that the phrase was indefinite. (R&R 22 n.13.)

Plaintiff's argument misapplies the well-accepted claim construction standards and reads Judge Lloret's ruling out of context. The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in light of the specification and prosecution history. Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012). If, however, there is no ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history, such a claim becomes indefinite because the language "might mean several different things" and the patent itself identifies "no informed and confident choice" among those potential meanings. Nautilus, Inc., 134 S. Ct. at 2130 n.8 (citation omitted). Thus, as noted above, in order to overcome an indefiniteness challenge, "the patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select." Dow Chem., 803 F.3d at 630.

Applying these standards, the court in Otsuka Pharm. Co., Ltd. v. Torret Pharms. Ltd., Inc., 151 F. Supp. 3d 525 (D.N.J. 2015) attempted to construe the meaning of the analogous term "mean particle size," recognizing that—as a general term—it was susceptible "to multiple measurements, each of which could yield varied results." Id. at 546. The plaintiff in that case—like Defendant here—took the position that the term meant volume weighted mean particle size, which it claimed was the default meaning to one of ordinary skill in the art. Id. at 544. The patent itself, however, made no connection between "mean particle size" and volumetric measures, and it failed to instruct on the manner in which to characterize the "size" of the particle, which could be measured by an array of commonly used means. Id. at 546–47. Finding that neither the intrinsic nor the extrinsic evidence guided a skilled practitioner on how to measure "mean particle size," and recognizing that there was a "clear absence of a convergence upon that convention in the field," the court found

that this was the "hallmark of an indefinite term." The court thus concluded that the term "mean particle size" was indefinite. Id. at 547–48.

Similar to Otsuka, the parties here dispute the meaning of the term "average particle size." Judge Lloret remarked that a person of ordinary skill in the art could read it to have one of several meanings including: a simple arithmetic mean, a volume weighted average, or a surface area weighted average. Thereafter, Judge Lloret rejected both parties' proposed constructions. Dismissing Defendant's request to interpret the phrase as meaning "volume weighted average," Judge Lloret noted that the patent did not explicitly mention volume weighted averaging and that using an arithmetic average made sense in the context of the process claimed by the patent. (R&R 10, 12.) Dismissing Plaintiff's request to interpret the phrase as meaning "arithmetic average," he also found that parts of the patent specification—including Figure 1 discussed below—suggested that the inventors intended "average particle size" to mean something other than an arithmetic mean. (R&R 16–17.)

Contrary to Plaintiff's argument, [3] at no point did Judge Lloret opine that a skilled artisan would understand "average particle size" meant an arithmetic mean. Rather, Judge Lloret found that, although the term "average particle size" signifies the arithmetic mean to "*an ordinary*

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[3] At the claim construction hearing in this case, Plaintiff relied on the pre-Nautilis Federal Circuit case of Osram GmbH v. Int'l Trade Comm'n, 505 F.3d 1351 (Fed. Cir. 2007), wherein the Federal Circuit was called upon to review the construction of the term "mean grain diameter." Finding that the term meant an arithmetic measure, the Court found guidance both in the specification and the purpose of the product. Id. at 1357. Specifically, the Federal Circuit remarked that "all of the experts agreed that the volume-based measure is more sensitive to large particles, which do not function in the invention, and that the number-based measure is more sensitive to the size and distribution of the particles that perform the inventive function. There was no contrary evidence." Id.

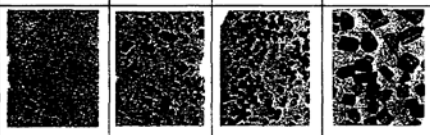
Here, by contrast, the patent's purpose and specification do not provide such guidance and the parties' experts do not agree on which measurement works better in the patent.

speaker of English," the term has been commonly used *in the art* to refer to both simple arithmetic mean and to a weighted average. (R&R 6, 9–10 (emphasis added).) As neither intrinsic nor extrinsic evidence identified an informed or confident choice among those contending forms of measurement, I conclude that Judge Lloret correctly deemed the term indefinite.

3. Whether the R&R Ignored Significant Facts Regarding Figure 1 of the Patent

Plaintiff next argues that the R&R improperly analyzed Figure 1 of the patent-in-suit to reach the conclusion that Plaintiff's proposed construction could not have been used to calculate the average particle sizes contained in Figure 1.

Specifically, Figure 1 of the patent shows the following:

		①	②	③	④	Control
[row 2]	Particle size of crystals added (μm)	30	45	70	110	–
[row 3]	Addition amount (g/l)	5.5	5.5	5.5	5.5	–
[row 4]	Photograph of crystals added					–
[row 5]	Specific surface area of crystals added (m^2/cm^3)	0.24	0.16	0.10	0.07	–
[row 6]	Total surface area of crystals added (m^2/L)	0.86	0.57	0.36	0.25	–
[row 7]	Photograph of culture after the completion of culturing					
[row 8]	Recovery rate of crystals (%)	92.1	92.6	87.1	82.1	33.4
[row 9]	Dry content (%)	98.6	98.3	96.3	96.5	83.9
[row 10]	Dry cell amount (%)	1.5	1.1	2.5	2.2	10.7

The patent's description of Figure 1 explains that it "show the relationship between the *average particle size*, specific surface area and total surface area of the crystals of the amino acid added . . ." ('723 patent, 2:62–64 (emphasis added).) Upon consideration of the evidence presented at the Markman hearing, Judge Lloret found that the average particle sizes referred to in

the second row of Figure 1 were not calculated using an arithmetic means. (R&R 15.) He thus concluded that "when the phrase 'average particle size' is used in the description of Figure 1 . . . it is not referring to an arithmetic mean." (Id. at 16.) In turn, he found that the patent specification did not support Plaintiff's construction of that term.

Plaintiff alleges that there are three errors regarding Judge Lloret's analysis of Figure 1. First, it contends that Figure 1 depicts the particle size of the crystals added in two ways: row two—depicting rough approximations of the particle size used in each experiment, and row four—providing scaled photographs of the crystal added so that the crystal sizes could be measured directly. According to Plaintiff, Judge Lloret focused only on the approximations in the second row, but never mentioned the scaled photographs, thus rendering his analysis incomplete.

Plaintiff, however, identifies no evidence to support the proposition that the photographs in row four of Figure 1 were intended to convey average particle size. Indeed, the specification explicitly provides that Figure 1 "shows the relationship between the average particle size [*i.e.*, row two], specific surface area [*i.e.*, row five] and total surface area [*i.e.*, row six] of the crystals of the amino acid added and the form [*i.e.*, rows nine and ten] and recovery rate [*i.e.*, row eight] of the crystals of the amino acid accumulated in the medium." ('723 patent, col. 2, lines 62:66.) The specification then notes that, in the photographs [*i.e.*, rows four and seven], the vertical side "represents 1000 μm," to explain the scale of magnification. (Id. at lines 66–67.) Because the specification does not reflect that the scaled photographs were intended to represent average particle size, Judge Lloret correctly disregarded them in his analysis.

Second, Plaintiff contends that the particle size numbers in Figure 1 were intended to convey "rough approximations of the particle size" as opposed to average particle size. (Pl.'s Objs. 6.) This unsupported characterization is undermined not only by the patent specification itself,

which identifies the row two numbers as being average particle size, but also by extrinsic evidence from the co-inventor of the '723 patent, who testified that the values in row two of Figure 1 are average particle sizes. (D.I. 80, Ex. 12, Dep. of Ryo Ohashi 66:12–69:17.)

Finally, Plaintiff asserts that "Figure 1 is not an embodiment, and, as noted, is mere data." (Pl.'s Objs. 6.) This statement, however, is directly contradicted by the specification, which explicitly states that "[c]ertain embodiments of the present invention are illustrated in the following examples." ('723 patent, col. 9 line 31–col. 10, line 38.) Example 2 beneath that statement uses crystals of L-glutamine "having the average particle size shown in in FIG. 1" as crystals added to the medium. Example 2 then goes on to repeatedly reference Figure 1 as demonstrating an embodiment of the invention. While such an embodiment cannot be construed to limit the claim, "[a] claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever correct." Globetrotter Software, Inc. v. Elan Computer Grp., Inc., 362 F.3d 1367, 1381 (Fed. Cir. 2004) (internal quotations omitted). Judge Lloret therefore correctly found that construing Figure 1 to embody use of average particle size that was not derived via arithmetic means undermined Plaintiff's proposed construction of that term.

4. Whether the R&R Erred in Relying on Communications with Foreign Patent Offices

Plaintiff's last objection takes issue with Judge Lloret's reliance on statements made by Plaintiff in foreign patent proceedings regarding the phrase "average particle size." Specifically, in European patent proceedings concerning a closely related patent with an identical specification, Plaintiff's expert, Dr. Richard Rosseau commented on the use of laser diffraction to measure particle size. In doing so, he opined that "average particle size" means "volume weighted average particle size." Although Judge Lloret recognized that statements made in European patent proceedings "should be used cautiously" because of differing patent standards, and that the

statement does not constitute a disclaimer, he properly found that Plaintiff's two "diametrically opposed positions about the meaning of the same phrase" had probative value and strongly suggested the claim was indefinite. (R&R 17–18.) Plaintiff now challenges Judge Lloret's conclusion on several grounds.

First, Plaintiff contends that Judge Lloret improperly relied on the statements to the foreign patent office—which constitute extrinsic evidence—to undermine the plain and ordinary meaning of the phrase—which constitutes intrinsic evidence. This argument, however, again misinterprets the R&R's findings. As explained in detail above, the ordinary meaning, for purposes of claim construction, "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313. Judge Lloret found that, although the term "average particle size" signifies the arithmetic mean to "*an ordinary speaker of English*," the term "average particle size" has been commonly used *in the art* to refer to both a simple arithmetic mean and a weighted average. (R&R 6, 9–10 (emphasis added).) Thus, given the ambiguity in the intrinsic evidence, Judge Lloret correctly consulted the extrinsic evidence in the form of the European patent statements.

Second, Plaintiff contends that Judge Lloret improperly gave more weight to the extrinsic evidence over the clear definition in the intrinsic evidence. This is inaccurate. Judge Lloret found that "both intrinsic and extrinsic evidence demonstrate that there is ambiguity about whether the phrase 'average particle size' refers to arithmetic mean or something else." (R&R 22.) He remarked that while a plain language reading of the term seemed to disclose an arithmetic mean, Figure 1 of the specification—which is part of the intrinsic evidence—appeared to disclose something other than use of arithmetic mean to determine "average particle size." (R&R 14–17.)

Given the inherent ambiguity in the intrinsic evidence, Judge Lloret appropriately sought guidance from the extrinsic evidence. See Markman, 52 F.3d at 980 (holding that if ambiguity still exists after considering all the intrinsic evidence, the court may rely on extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises"). Ultimately, he found that although Plaintiff's position in the European patent proceeding did not legally preclude its contrary position in this case, such extrinsic evidence underscored the fact that the claim was susceptible to different definitions and, thus, was indefinite.

Finally, Plaintiff asserts that because European patent standards are different than in a U.S. proceeding, statements made in the European proceeding are irrelevant to claim construction here. The Federal Circuit, however, has recognized that "statements made before foreign patent offices are sometimes relevant to interpreting the claims." Starhome GmbH v. AT&T Mobility LLC, 743 F.3d 849, 858 (Fed. Cir. 2014); see also Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1374 (Fed. Cir. 2005) (relying on party admissions before the European Patent Office to construe the claims). The Court has cautioned that such statements may be "irrelevant to claim construction" if the statements "were made in response to patentability requirements unique to [foreign] law." Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1290 (Fed. Cir. 2006). Nonetheless, the Federal Circuit has "routinely approved reliance upon statements in foreign prosecutions where they constituted 'blatant admissions' directed at the relevant art." Baxter Healthcare Corp. v. HQ Specialty Pharma Corp., 133 F. Supp. 3d 692, 703 (D.N.J. 2015) (citing cases).

Plaintiff's foreign patent statements here constituted "blatant admissions." During the foreign patent proceedings, Plaintiff's expert, Dr. Rousseau, was asked what the claim term

"average particle size" meant in the context of the patent. He responded that, based on the specification, the average was a "volume-weighted" quantity.[4] This statement did not involve any issue unique to foreign patent law, but rather was a response to a technical question regarding what a specific term meant in the context of the same patent specification. Accordingly, I find no error in Judge Lloret's consideration of and reliance on this statement in his claim construction.

5. Conclusion as to "Average Particle Size"

For all of the above reasons, I find that Judge Lloret's thorough construction of the term "average particle size" led to the correct finding that the term is ambiguous. The conflicting intrinsic evidence failed to inform those skilled in the art about the scope of the invention with reasonable certainty, and the extrinsic evidence did not resolve this ambiguity. Consequently, claims 1 and 2 of the patent-in-suit, in which this term appears, are legally invalid for indefiniteness. I will therefore overrule Plaintiff's objections and adopt the R&R as to this term.

B. Whether Judge Lloret Erred in His Construction of the Term "[A]dding crystals of the amino acid . . . to the medium"

Defendant next objects to Judge Lloret's construction of the term "adding crystals of the amino acid . . . to the medium." Judge Lloret broadly construed the term as meaning "[i]ntroducing crystals to the medium that were not there before, which are the same crystals that the claim later requires 'grow . . . and accumulate in the medium.'" (R&R 25.) In doing so, he rejected Defendant's contention that the term meant "putting crystals of the amino acid . . . into the medium. This term does not encompass crystals that form in the medium." He reasoned that there are

[4] Plaintiff argues that Dr. Rousseau's statements "were made in response to a very specific question about a very specific portion of the specification, not about Average Particle Size in general," and thus are not probative of the term "average particle size." (Pl.'s Objs. 9.) There is no reason to believe, however, that the term "average particle size" has different meanings in different parts of the same specification.

multiple ways to introduce crystals into a broth, including pouring or dumping crystals, pouring oversized crystals into the broth and then breaking them up with agitator blades, or shocking the amino acids in a solution to form seed crystals. As the patent did not disavow any of these three methods to "add" crystals to the broth, Judge Lloret found that the term "adding" in the patent could not be construed to exclude any of the methods.

Defendant now posits that this construction was flawed on two levels. First, it asserts that its proposed construction of "adding"—which excludes from the term any crystals that form in the medium—is the ordinary meaning of the term, as evidenced by every example in the '723 patent, dictionary definitions, and the scientific literature. Second, Defendant contends that there is no mechanism by which to apply Plaintiff's construction to a commercial process.

1. Whether the Evidence Required Adoption of Defendant's Construction

Defendant first asserts that, aside from the opinion of Plaintiff's expert, all evidence of record is either irrelevant or supports Defendant's proposed construction that "adding crystals of the amino acid . . . to the medium" means putting crystals, formed outside of the medium, into that medium. Defendant notes that each of the fifteen descriptions used in the specification of "adding" crystals involves putting pre-existing crystals into the broth/medium, which is consistent with the dictionary definition of the term "add." It claims that "[t]here is no objective evidence that one of ordinary skill in the art would have understood the term . . . to include shock-seeding, breaking crystals through secondary nucleation, or other forms of generating new crystals out of the amino acid that is already in the medium." (Def.'s Objs. 2.)

This argument disregards certain claim construction principles. "[T]he specification is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (citations and quotations omitted); see

also Merck & Co. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("[C]laims must be construed so as to be consistent with the specification, of which they are a part."). Nonetheless, it is well established that limitations from the preferred embodiments or examples from the specification should not be read into the claims because "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." Phillips, 415 F.3d at 1323. The only two exceptions to this general rule are if the patentee sets out a special definition and "acts as his own lexicographer," or if the patentee disavows the full scope of a claim term in the specification or during prosecution. Thorner, 669 F.3d at 1365.

Neither of these exceptions exist here. The claim language does not describe the method by which seeds are "added" to the broth or medium, and, as noted in the R&R, there is no dispute that "adding" crystals can be done in multiple ways including pouring, breaking up, and shock seeding. To act as his own lexicographer, "[i]t is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term." Id. Thus, the mere fact that the various descriptions of "adding" crystals in the patent specification involve putting pre-existing crystals into the broth/medium does not mean that that limitation should then be read into claims. Had the inventors wanted to limit "adding" to the introduction of pre-existing crystals, they clearly knew how to do so and could have included that language in the claims themselves.

Likewise, Judge Lloret correctly found that there was no disavowal. Under the second Thorner exception, "the claims must not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1347 (Fed. Cir. 2015) (citations

and quotations omitted). Although Defendant argues that nothing in the intrinsic record broadens the ordinary meaning of the term "adding . . . to" to mean "introducing" or "forming in," the plain English meaning of the term, however, is not the proper construction; rather it is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. Because the term "adding" could mean breaking up or shock seeding to one of ordinary skill in the art in the context of the patent, and because the claim language does not disavow this meaning, it would have been improper for Judge Lloret to read in a limitation to the term "adding" from any of the examples in the specification.

In short, "[w]here, as here, the written description and prosecution history fail to express a manifest exclusion or restriction limiting the claim term, and where the written description otherwise supports the broader interpretation, [I am] constrained to follow the language of the claims." Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 326 F.3d 1215, 1223 (Fed. Cir. 2003) (internal quotations omitted). As I cannot import limitations from the embodiments or examples within the specification, I will adopt Judge Lloret's broad reading of the term "adding."

2. Whether There Is No Practical Application of the Claim as Construed

In its second challenge to Judge Lloret's construction, Defendant contends that the construction cannot be practically applied to a real-life process to determine whether the crystals introduced in the medium (by any method) meet the average-particle size range specified in the claims. It asserts that, as conceded by Plaintiff, the agitator blades that stir the crystals in the broth continually cause crystal nuclei to break off of the crystals in the broth, *i.e.* secondary nucleation, and thus there is no means by which to ascertain the size of the crystals when they were first "introduced," either as an external crystal added to the broth or as a crystal formed internally within a broth. According to Defendant, its construction avoids this problem by interpreting the term

"adding" to mean putting crystals formed outside of the broth into the broth. Defendant reasons that, under this definition, the "average particle size" can be determined by measuring the to-be-added crystals prior to putting them in the broth.

This argument, however, goes not to the construction of the claim, but rather the validity of the claim. Claim construction is a matter of law used to define the meaning and scope of the claims in a patent. Markman, 52 F.3d at 976. "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips, 415 F.3d at 1312 (internal quotation marks omitted). The focus of a court's analysis "must therefore begin and remain centered on the language of the claims, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'" Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2). It is not appropriate during claim construction—particularly absent the requisite evidence—to determine whether there exists a commercial process by which to apply Plaintiff's construction.

Moreover, the record does not clearly demonstrate that no such commercial process exists by which to measure average particle size of crystals once they are in the broth. Defendant contends that Plaintiff's expert, Dr. Doherty, was unable to explain how to determine average particle size of the crystals when some originate as external crystals and others originate as new crystals within the broth. A fair reading of Dr. Doherty's testimony, however, simply reveals that he was unable to answer the question at that time:

> Q. So in the context of Claim 1 of the '723 patent, what particles go into the calculation of average particle size?
> A. The particles that are introduced as seeds.
> Q. So in your opinion, that includes the seed crystals that are added externally?
> A. Yes.

> Q. Crystals that form through secondary nucleation?
> A. If that's your primary means of creating seeds, I would say yes. If it's not your primary means of creating seeds, then I don't have an opinion on that.
> Q. How do you determine if that's your primary means of creating seeds?
> A. Well, if you're not putting seeds in from the outside world, then you have to be doing it some other way, and then you have to know what you did and what the size range was in order to know whether you created seeds or not.
> Q. What if you do both; you add external crystals and you also experience secondary nucleation? In that situation, would both the crystals that were added externally and the crystals formed through secondary nucleation be taken—into account in calculating average particle size?
> A. I actually haven't formed an opinion about that. I would need to think more carefully and perhaps review more literature to answer your question.

(D.I. 103-1, 125:23–127:7.) Nothing in this testimony clearly demonstrates that determining the size in these hypotheticals was impossible.

Further, as Judge Lloret noted following the claim construction hearing, "a common industrial technique is to use an 'in-line' measurement technique, such as FBRM, to measure crystal seeds directly in a vessel, rather than pulling out a sample to measure on a laser diffraction machine." (R&R 13.) Defendant does not explain why such a method would not work with Plaintiff's construction of this claim.

I find that Judge Lloret properly ascribed a broad meaning to the term "[a]dding crystals of the amino acid . . . to the medium." Such a construction comports with the term's ordinary meaning in the context of the patent to one skilled in the art and does not import limitations from preferred embodiments into the claims.

IV. CONCLUSION

For all of the foregoing reasons, I will overrule both parties' objections and adopt the R&R in its entirety. An appropriate Order follows.